REMARKS

Claims 12, 14, 15 and 39 are pending. Reconsideration and immediate allowance of the pending claims in view of the remarks below is respectfully requested.

The Invention is Useful to Treat Prostate Cancer

Claims 12, 14-15, and 39 were rejected under 35 U.S.C. § 101 because the claimed invention allegedly is not supported by either a specific and substantial asserted utility or a well established utility. Applicants traverse this rejection and again assert that the claimed protein is useful as a target on prostate cancer cells.

Asserted Utility

The Office noted in the latest Action that the specification asserts that polypeptides of the invention can be used to generate antibodies for detecting 84P2A9 overexpression or the metastasis of prostate cancer cells or other cancer cells which express the gene. Office Action, page 2. This statement is factually accurate, but completely irrelevant to the prosecution of the present case.

Applicants asserted in the previously filed response that the claimed protein was useful as a therapeutic target on prostate cancer cells. "[A]n applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. § 112." M.P.E.P. § 2107.02. The fact that other utilities are asserted in the specification is irrelevant because the asserted utility of the protein as a therapeutic target on prostate cancer cells is sufficient to satisfy the statutory requirements. *See, e.g., In re Gottlieb*, 328 F.2d 1016, 1019 (CCPA 1964).

Applicants reiterate the assertion that the claimed protein is useful as a target on cancerous prostate cells. Although Applicants readily admit that there are other uses for the claimed subject matter, for the purposes of prosecution in this case, Applicants rely solely on the presently asserted utility. In view of this, the alleged usefulness of the claimed subject matter as a diagnostic is not relevant to the prosecution of the present case.

Nexus of Claimed Protein and Prostate Cancer

The Office admitted in the Action that Applicants have shown a nexus between polynucleotide expression and a diseases state. Office Action, page 3. Yet, the Office alleged that

the present specification has failed to disclose a correlation between a specific disorder and "an altered level or form of the claimed peptide." *Id.* The Office also says that "[o]ne needs to know, e.g., that the claimed polypeptide is present only in cancer tissue to the exclusion of normal tissue." *Id.* Applicant's respectfully disagree with the Office's position with regard to satisfying the statutory requirement of §101.

Those of ordinary skill in the art recognize that the prostate is a gland which secretes a component of semen. Skilled artisans also recognize that the prostate is a completely disposable organ, which means that a human male can live without a functioning prostate. This point is supported by the common practice of surgically removing cancerous prostates from individuals diagnosed with prostate cancer. (See the National Cancer Institute's web site at http://www.cancer.gov/cancertopics/pdq/treatment/prostate/Patient/page4#Keypoint14). It should also be noted that there are a number of art recognized techniques that can be used to diagnose prostate cancer. These include the digital rectal exam (DRE), the prostate-specific antigen (PSA) test and transrectal ultrasound. (See the National Cancer Institute's web site at http://www.cancer.gov/cancertopics/pdq/treatment/prostate/Patient/page1).

Additionally, Applicants note that there are a number of antibodies on the market that are used to treat cancer that cross react with normal tissue (i.e. Rituxan® (Genentech) and Erbitux® ImClone). Applicant's note that the Full Prescribing Information for Rituxan® clearly states that the Role of Rituxan® "Binds to CD-20 positive malignant and **normal** B-cells". (*See*, http://www.gene.com/gene/products/information/oncology/rituxan/moa.jsp) (**Emphasis added**). Additionally, the package insert for Erbitux® states, "Cetuximab (i.e. Erbitux®) binds specifically to the EGFR on **both normal and tumor cells** and competitively inhibits the binding of epidermal growth factor (EGF) and other ligands, such as transforming growth factor-alpha." (See, http://www.bms.com/cgi-in/anybin.pl?sql=select%20PPI%20from%20TB_PRODUCT_PPI%20where%20PPI_SEQ=106&key=PPI). (**Emphasis added**). Accordingly, the commercial success of these antibodies demonstrates that this cross-reactivity is not alone sufficient to render such an antibody useless. Antibodies that recognize the claimed protein can be used alone or labeled with toxins,

radioisotopes or other chemotherapeutic agents to inhibit the growth of prostate cancer cells expressing the claimed protein.

Applicants assert that the claimed protein is useful as a target on prostate cancer cells. One exemplary mechanism by which the present protein could find use provides that the claimed protein is used to generate antibodies, which bind specifically to the claimed protein.[1] In another aspect of this mechanism, the antibodies so generated are labeled with an agent, such as a chemotherapeutic compound or a radioisotope. The prostate cancer cells are exposed to the labeled antibodies, which bind to the cells. The proximity of the labeled antibodies to the cells causes them to suffer damage, and ultimately die.

Under this mechanism it is completely irrelevant whether normal, non-cancerous prostate cells express the claimed protein because the idea of the treatment is to kill as many cancerous cells as possible. The presence of non-cancerous cells that express the claimed protein may actually potentiate the effectiveness of the labeled antibodies by bringing more of the label in proximity to cancer cells which are located near the non-cancerous cells. As such, the Office insists that a difference in expression of the claimed protein between cancerous and non-cancerous cells is required; this insistence is misplaced.

Applicants have demonstrated that the claimed protein is expressed by cancerous prostate cells. Data supporting this point is found in the specification in the form of mRNA expression as well as in the Rule 1.132 declaration of Dr. Morrison, which was provided with the last response. Dr. Morrison's declaration also clearly demonstrates that antibodies which bind to the claimed protein are capable of binding prostate cancer cells. As the Office admitted in the latest Office Action, "Applicants have shown that the claimed protein can be detected on prostate cancer cells using immunohistochemistry." (Office Action, page 5). Accordingly, Applicants have demonstrated that the claimed protein is present and detectable on prostate cancer cells.

The data and comments provided above clearly establish a link between the claimed protein and prostate cancer. Because of this nexus and the examples set forth above of similar antibodies

[1] This exemplary mechanism is provided solely to illustrate the usefulness of the invention and does not constitute a limitation of the claims.

that are commercially available, the usefulness of the claimed invention is clearly shown by a preponderance of the evidence. Accordingly, Applicant's request the Examiner to withdrawal the rejections under §101 and §112.

Deposit Issues

The Office has rejected claims 14-15 and 39 under 35 U.S.C. § 112, first paragraph for an alleged lack of enablement. Regarding deposits:

> "A deposit made before or during pendency of an application for patent shall be made for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository. In any case, samples must be stored under agreements that would make them available beyond the enforceable life of the patent for which the deposit was made." 37 C.F.R. § 1.806.

The Office has noted that ATCC deposit receipt which indicates that the deposit of PTA-1151 will be held for 30 years in the patent depository. By the very nature of the patent depository, deposits made therein in support of a patent are necessarily available to the public. Nevertheless, to facilitate prosecution, Applicants' representative asserts that the deposited material will remain deposited with the ATCC for 30 years from January, 2001 and will be publicly available.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 511582000100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By _____

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